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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/509,482 | 09/15/2000 | Linda Anne Crofts | 1871-130 | 9624 |

7590 12/10/2001

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EXAMINER

ULM, JOHN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1646

DATE MAILED: 12/10/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/509,482

Applicant(s)
Crofts et al.

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☒ Claims 1-17 and 19-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Claims 1 to 25 are pending in the instant application. Claims 9, 10, 13, 15 and 17 to 20 have been amended and claim 25 has been added as requested by Applicant in Paper Number 5, filed 15 September of 2000.

Claims 18 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must depend from previous claims in the alternative only. See MPEP § 608.01(n). Claim 18 depends from claim 15 and from claim 1. Accordingly, the claim 18 has not been further treated on the merits.

Claims 15 to 17 , 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. If any of these claims are elected, Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. Each of these claims can be infringed by a composition which does not infringe every claim from which they depend. For example, claim 16 can be infringed by an antibody which does not infringe the protein of claim 15 or the polynucleotide of claim 1. See M.P.E.P. 608.01(n)III.

Claims 3, 4 and 21 to 24 are objected to as reciting an improper Markush Group.

M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish* , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi* , 3 USPQ2d 1059 (Bd. Pat. App. &

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Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

The sequences recited in the Markush Groups of these claims do not appear to share a common structural feature which serves as a basis for a common utility.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 to 4, 9 to 14 and 21 to 24, only in so far as they are drawn to an isolated polynucleotide comprising exon 1d (SEQ ID NO:1), classified in class 435, subclass 69.1.
- II. Claims 5 to 14 and 21 to 24, only in so far as they are drawn to an isolated polynucleotide comprising exon 1f (SEQ ID NO:5), classified in class 435, subclass 69.1.
- III. Claims 5 to 14 and 21 to 24, only in so far as they are drawn to an isolated polynucleotide comprising exon 1e (SEQ ID NO:6), classified in class 435, subclass 69.1.
- IV. Claim 15, drawn to a human protein, classified in class 530, subclass 350.
- V. Claim 16, drawn to an antibody, classified in class 530, subclass 388.22.
- VI. Claim 17, drawn to a transgenic animal, classified in class 800, subclass 2.

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- VII. Claims 19 and 20, only in so far as they are drawn to a polynucleotide which is complementary to a portion of a polynucleotide comprising exon 1d (SEQ ID NO:1), classified in class 536, subclass 24.31.
- VIII. Claims 19 and 20, only in so far as they are drawn to a polynucleotide which is complementary to a portion of a polynucleotide comprising exon 1f (SEQ ID NO:5), classified in class 536, subclass 24.31.
- IX. Claims 19 and 20, only in so far as they are drawn to a polynucleotide which is complementary to a portion of a polynucleotide comprising exon 1e (SEQ ID NO:6), classified in class 536, subclass 24.31.

The inventions are distinct, each from the other because:

Inventions I to IX are nine different compositions each of which can be made and used without any one or more of the other claimed composition. Lack of unity is shown by the fact that these nine different compositions lack a common utility which is based upon a common structural feature lacking from the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800